# Exhibit 73

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF RHODE ISLAND

STATE OF NEW YORK, et al.

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

Case No. 1:25-cv-00196

## **DECLARATION OF JOHN DOE 7**

I, John Doe 7, declare under the penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct:

- 1. I was employed by the Center for Tobacco Products (CTP), within the U.S. Food & Drug Administration (FDA). I have personal knowledge of the facts set forth in this declaration, and if required to testify, would and could competently do so.
- 2. I am submitting this declaration pseudonymously because I fear retaliation. But if the Court would like to know my name or previous position at CTP, I would be willing to provide it *ex parte* and under seal.
- 3. I submit this Declaration in support of the States' Motion for a Preliminary Injunction.

## **Professional Background**

4. I have worked in public health for over 14 years.

5. I am providing this declaration to explain the impacts of the reductions in force (RIFs) of April 1, 2025 on the operations of CTP. The April 1 RIFs have brought much of CTP's work to a halt. These impacts will be felt by the states as well as by their residents, as CTP will no longer be able to support public education campaigns, award contracts with states to conduct retailer inspections, and collect and manage user fees.

## CTP's Mission and Work Prior to April 1, 2025

- 6. CTP oversees the implementation of the Family Smoking Prevention and Tobacco Control Act by, among other things, setting performance standards for tobacco products, reviewing premarket applications for new and modified risk tobacco products, requiring new warning labels, and establishing and enforcing advertising and promotion restrictions.
- 7. Pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 387s, CTP is funded entirely by tobacco user fees collected from domestic manufacturers and importers of cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigar, and pipe tobacco. These appropriated user fees are available only for the purpose of paying costs related to tobacco regulation activities and are the only funds authorized to be made available for this same purpose. 21 U.S.C. § 387s(c)(2)(A)-(B).
- 8. Among other duties, CTP conducts compliance checks on vendors and retailers to ensure that tobacco products are not sold to those under the age of twenty-one, reviews premarket applications for new tobacco products before they can be marketed in the United States, enforces advertising and promotion restrictions, and educates the public about the risks of tobacco use including the dangers of cigarettes, e-cigarettes and other tobacco products.

- 9. Further, CTP collaborates with the Centers for Disease Control and Prevention (CDC) in administering the National Youth Tobacco Survey (NYTS), a national data collection program that informs states' tobacco prevention policies and regulatory efforts.
- 10. CTP is administered by the FDA within the U.S. Department of Health and Human Services (HHS).
- 11. CTP is led by a director and oversees five offices: the Office of Management,
  Office of Regulations, Office of Science, Office of Health Communication and Education, and
  the Office of Compliance and Enforcement.
- 12. The Office of Regulations promulgates regulatory policies on tobacco. The Office of Regulations also handles public comment by using public dockets announced in the Federal Register to gather information from the public and stakeholders on draft guidance, proposed regulatory actions, rules, and other topics related to the regulation of tobacco products.
- 13. The Office of Management oversees CTP's budget and fiscal management, contracting, travel, and hiring. It also contains CTP's call center, mail center, and IT services. Significantly, it assesses and collects user fees which fund all the work of CTP, including activities related to public education (including public education campaigns and communicating CTP activities), regulatory science (including research, product review, and developing the science to support regulations and guidance), compliance and enforcement (including tobacco retailer inspections, manufacturer and import inspections and enforcement, and advertising and labeling surveillance), and administrative programs. The Office of Management has 6 groups: Division of Financial Management; Acquisitions and Assistance; Management Logistics Group; Management and Analysis Group; Human Capital Team; and IT Services.

- 14. Within the Office of Management, the Division of Financial Management formulates CTP's budget and oversees execution of the budget. It certifies funds, monitors payroll, and ensures CTP is following federal appropriations laws and responds to congressional inquiries related thereto. The Acquisitions and Assistance Group creates and submits contract and grant packages for award and submits funding for those awards. The Management Logistics Group oversees travel, timekeeping, has oversight of invoice receiving/payment, contains the document control center handling the mail, and manages the call center. The Human Capital Group oversees human resources, which submits packages to hire and track staff, manages staff benefits, and oversees training required by HHS regulations. The Management and Analysis Group oversees ethics filings among other activities. The IT Services Group manages CTP's centralized IT systems, ensures CTP compliance with federal and HHS regulations related to IT systems, and also manages highly specialized systems including the tobacco inspection management system and the tobacco user fee system.
- 15. The Office of Science employs scientists to review premarket tobacco product applications (PMTAs), which can be submitted by any person for any new tobacco product seeking an FDA marketing order. Further, the Office of Science is directly involved with administering the NYTS in collaboration with CDC.
- 16. The Office of Health Communication and Education's work involves communication about CTP's activities, public education campaigns such as "The Real Cost" campaign, and the distribution of important messages and information on the regulation of tobacco products as well as the health risks associated with tobacco use. The Office of Health Communication and Education has three divisions: the Division of Public Health Education, the

Division of Research and Evaluation, and the Division of Regulatory Communication. They also have a "front office" for administrative personnel and FOIA responsibilities.

17. The Office of Compliance and Enforcement monitors retailer, manufacturer, importer, and distributor compliance with federal tobacco laws and regulations and takes regulatory or enforcement actions when violations occur. Such regulatory or enforcement actions include issuing warning letters and civil money penalties, placing tobacco products on an import alert, and assisting the Office of Inspections and Investigation in performing seizures of unauthorized products at the border.

#### The April 1, 2025, RIFs and Effects on CTP

- 18. On April 1, 2025, at least 100 employees—myself included—received RIF notices and are awaiting final separation from federal employment. Employees who had not already filed for retirement or early retirement and who received a RIF notice included employees from CTP's five offices.
- 19. CTP's Office of Management and Office of Regulations have been eliminated because all of their employees either separated from service before April 1, or received RIF notices on April 1. CTP's Office of Compliance and Enforcement lost about 25 to 40 employees. Employees within the Office of Compliance and Enforcement's Division of Business Operations, which handles civil monetary penalties and administers contracts critical to CTP's enforcement efforts were RIFed but their RIF notices were rescinded on May 9, 2025. The Office of Health Communication and Education also lost employees.
- 20. I have not received any communications from HHS about the specific reason why the Office of Regulation was eliminated, nor any indication that the Department intends to

reinstate the RIFed employees. The same is true of all other CTP employees that I have communicated with about the RIF.

#### The April 1 RIFs Have Devastated CTP's Work

- 21. The RIFs have effectively halted much of CTP's work because most employees in the Office of Management or the Office of Regulations were immediately placed on administrative leave pending final separation and are unavailable to carry out the work. Of crucial importance to CTP's operation, without employees in the Office of Management to assess and collect the tobacco user fees, CTP runs the risk of losing its sole funding source.
- 22. The RIFs have impacted CTP's Office of Management's ability to track user fees, support contract acquisitions, and monitor payroll. For instance, the Office of Management will no longer be able to create contract actions for states and territories on retailer inspections as required by statute. Because the entire Office of Management is terminated, there is no one left to certify funds, manage the tobacco inspection management system and e-submission system, or ensure that CTP follows federal appropriations laws. Further, staff are not available to create a fiscal year 2026 execution budget, recruit new staff, monitor timekeeping, ensure timely receiving/payment of invoices, and conduct oversight of CTP's document control center and call center.
- 23. Although at least some of the employees RIFed from the Office of Compliance and Enforcement have been reinstated, the RIFs within that Office nonetheless interrupted CTP's work. Contractor support is required for many enforcement activities including issuing warning letters and civil money penalties, conducting retailer and manufacturing inspections, and surveillance of tobacco advertising. These activities will be disrupted if support staff in the Office of Management are unavailable to ensure these contract actions are created and funded.

24. The employees managing crucial projects in the Office of Health Communication and Education have also been RIFed, leaving their work abandoned. This includes many of CTP's statutorily mandated functions. The RIFs have devastated the ability of CTP's Office of Health Communication and Education's Division of Public Health Education to run "The Real Cost" campaign, a national tobacco prevention advertising campaign that provided accurate and current information about the harmful effects of tobacco use. All of the employees working on the Campaign were RIFed on April 1, and without the necessary staffing and their expertise, "The Real Cost" campaign will not be able to continue its mission to reduce the lifetime risks of tobacco-related disease and death, and reduce smoking-related costs, which have saved more than \$53 billion dollars as a result of "The Real Cost" Campaign. Further, employees of the Office of Health Communication and Education will be limited in their ability to develop educational materials for industry and retailers about the laws pertaining to the sale of tobacco to anyone under age twenty-one. This work is not and cannot be duplicated elsewhere within FDA or the broader Department of Health and Human Services (HHS).

#### **Conclusion**

25. The April 1, 2025 RIFs have incapacitated several offices of CTP and some of its most crucial functions. Thus, CTP's work in tobacco use prevention is not being diligently completed. Without CTP's expertise, including that of experts such as toxicologists and epidemiologists, no other agency within FDA or HHS will carry out CTP's functions to provide guidance and support in tobacco-related death and disease prevention.

John Doe 7

Date: 5/19/2025